

## **REMARKS**

### **The Amendments**

Claims 1, 11 and 32 are amended to remove unnecessary language which renders the 35 U.S.C. §112 rejection moot, as discussed below. The amendments do not narrow the scope of the claims since the current claims do not exclude embodiments wherein the radionuclide component is part of a compound or complex. The amendments should not be interpreted as an acquiescence to any objection or rejection made in this application.

To the extent that the amendments avoid the prior art or for other reasons related to patentability, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art or otherwise unpatentable to applicants. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

### **The Restriction Requirement**

Applicants maintain their traversal of the restriction requirement. Although it is true that applicants had made a previous election of species, it is not true that the subject matter of the instant claims was previously subject to a restriction requirement. The Office Action refers to "earlier restrictions on August 20, 2002, and November 18, 2002". However, the action of August 20, 2002, was an election of species requirement, not a restriction, and the action of November 18, 2002, was a restriction of the kit claims subject matter of claims 23-31, which subject matter has been canceled. The current composition and method claims

were never previously restricted from one another in the previous prosecution consisting of five full Office Actions on the merits and one Advisory Action. Although the examination/search has apparently been limited to the elected species – due to the election of species requirement – there has been no indication that it has been limited only to the claimed compositions or methods. The previous prosecution indicates that both the composition and method claims – as to the elected species – have been searched and examined.

For the above reasons, applicants reiterate that the composition and method claims – as to the elected species – have already been fully searched and examined together by the USPTO on numerous occasions. Thus, applicants reiterate that there is not a serious burden of extra search and examination on the Examiner. Additionally, it is believed an absence of serious burden is further evidenced by the eventual need to rejoin the method claims. The method claims require the particulars of the composition claims and, thus, allowance of the composition claims would necessarily lead to allowance of the method claims. Because the method claims should, eventually, be rejoined, no added burden is seen in including them in the examination now. Should the restriction be maintained, applicants request that an indication be provided that rejoinder is appropriate should the composition claims be found allowable and the method claims require the particulars thereof. Additionally, applicants urge that the separate classification of the methods and compositions asserted in the Office Action does not, alone, support presence of a burden. In the absence of a serious burden, restriction is not proper and the restriction requirement should be withdrawn.

**The Rejection under 35 U.S.C. §112, second paragraph**

The rejection of claims 1-4, 6, 8-10, and 32-33 under 35 U.S.C. §112, second paragraph, is rendered moot by the above amendments. The amendments remove the

language giving rise to the rejection. To clarify, the "optionally as part of a compound or complex" language was initially provided to refer to the nature of the radionuclide. It was believed it would have been clear to one of ordinary skill in the art in light of applicants' disclosure that the radionuclide could be provided as an independent component or incorporated as part of a compound or complex containing the radionuclide; see, e.g., the examples in the disclosure where the Tc-99m radionuclide is complexed to the targeting agent. Since the "optionally" language appeared only in the claim clause directed to the radionuclide, it is not understood how this was interpreted as meaning the targeting agent or iodide components were optional. In any event, to avoid confusion, the "optional" language is removed from the claims. It was unnecessary anyway because the radionuclide term in the claims encompasses its presence in any form.

#### **The Rejection under 35 U.S.C. §102**

The rejection of claims 1-4, 10 and 32-33 under 35 U.S.C. §102, as being anticipated by Solanki (U.S. Patent No. 5,262,175) is respectfully traversed.

As discussed above, the targeting agent is not an optional component of the claimed compositions. Although this was believed to be clear in the previous claims, the removal of the "optionally.. " language by the above amendments leaves no room for doubt. As admitted in the Office Action, Solanki provides no disclosure regarding a targeting agent component according to the instant claims. Thus, Solanki does not anticipate the instant claims and the rejection under 35 U.S.C. §102 should be withdrawn.

#### **The Rejection under 35 U.S.C. §103**

The rejection of claims 6, 8 and 9 under 35 U.S.C. §103, as being obvious over